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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,499	04/27/2007	Kyogo Itoh	2006_1150A	2817

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,499	ITOH ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-19* is/are pending in the application.

4a) Of the above claim(s) *4,5,8-12 and 15-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment filed 4/1/09 has been entered into the record.

B. Claims 1 and 3-19 are pending. Claims 1, 2, 6, 7, 13 and 14 are the subject of this Office Action.

2. Specification/Sequence Listing

A. According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear on page 24, paragraph [0024], of the specification but are not identified by SEQ ID NO as required.

3. Claim Objections

A. Claims 1, 3, 6,, 7, 13 and 14 are objected to. Claims 1, 6 and 13 are unclear since they can be interpreted as (1) the peptide can both induce a cytotoxic T lymphocyte and induce an antibody, or (2) the pharmaceutical composition comprises both the peptide of claim 1 as well as an antibody. If the latter is true, it is not understood why a pharmaceutical composition would comprise both a peptide and an antibody to the peptide.

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claims 1, 3, 6 and 7 under 35 USC 112, first paragraph, regarding "derivatives" and "mutants" has been withdrawn in view of Applicants' amendments to cancel these terms.

B. Claims 1, 3, 6, 7, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an EGRF-derived peptide capable of inducing a cytotoxic T lymphocyte where the peptide consists of SEQ ID NO:1, 2, or 3, does not reasonably provide enablement

for the peptide consisting of SEQ ID NO:4 (elected) or 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Examiner had stated in the previous Office Action that Applicants were enabled for SEQ ID NO:1-5 with regard to being capable of inducing a cytotoxic T lymphocyte. However, upon further review, the Examiner was unable to find any guidance or working examples that SEQ ID NO:4 (elected) or 5 were able to perform the desired function. Given the distinct sequences of SEQ ID NO:1-5, it is not predictable to one of ordinary skill in the art that SEQ ID NO:4 and 5 would be capable of inducing a cytotoxic T lymphocyte given that SEQ ID NO:1-3 are capable of such. For these reasons, the Examiner concludes that undue experimentation would be required to practice the invention as claimed.

C. Claims 7 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition using SEQ ID NO:1-3 for the intended use of inducing a cytotoxic T lymphocyte, does not reasonably provide enablement for a pharmaceutical composition for use as a cancer vaccine where the peptide consisting of SEQ ID NO:1-3 as well as SEQ ID NO:4 (elected) or 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

First, the breadth of the claims is excessive with regard to being used as a cancer **vaccine** for any type of cancer (e.g. solid, blood-borne). Applicants have provided no guidance or working examples that the peptides of the invention are able to **prevent** any specific cancer, let alone any type of cancer. Figure 5 does show that some of these peptides (not SEQ ID NO:4) are cytotoxic against certain cancer cells. However, the claims are drawn to a vaccine (i.e. for the prevention of cancer) and there is no data to support this assertion. Given this, it is not predictable to one of ordinary skill in the art that the cytotoxic ability of the peptides would indicate that these peptides would be able to prevent cancer. For these reasons, the Examiner concludes that undue experimentation would be required to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 1, 3, 6 and 7 under 35 USC 112, first paragraph, regarding "derivatives" and "mutants" has been withdrawn in view of Applicants' amendments to cancel these terms.

6. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 13 and 14 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to add SEQ ID NOs.

7. Claim Rejections - 35 USC § 102

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' amendments to cancel the terms "derivative" and "mutant".

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647